

## **REMARKS/ARGUMENTS**

### **Status of the Claims**

Claims 1, 3, 5, 8, 11, 13, 15, 18, 21, 23, 25, 28, and 36-49 have been cancelled without prejudice or disclaimer. Claims 2, 4, 6, 9, 10, 12, 14, 16, 19, 20, 22, 24, 26, 29, 30, 32 and 34 have been amended. Claims 2, 4, 6, 7, 9, 10, 12, 14, 16, 17, 19, 20, 22, 24, 26, 27, and 29-35 are currently pending in this application.

All pending independent claims (Claims 4, 14, 24, and 31) make reference to SEQ ID NO:1.

Support for the amended claims may be found, at least, at Figures 4 and 6, the sequence listing and within the claims as originally filed.

### **Objections to the Specification**

The specification has been objected to for (1) containing embedded hyperlinks; (2) not containing a sequence identifier in Figure 6; and (3) containing a brief description on the legend of Figure 4.

Paragraphs [0057] and [0061] have been amended to remove embedded hyperlinks that were noted by Examiner. In accordance with Examiner's instructions, Figure 6 has been amended to include sequence identifiers and Figure 4 has been amended to remove the title for the graph.

Applicants therefore respectfully request that the Examiner withdraw the objections.

### **Claim Rejections Under 35 U.S.C. 112, first para**

The Examiner has rejected Claims 1-49 as originally filed alleging that these claims do not comply with the written description requirement and are also not enabled. Applicants first note that Examiner's rejection is moot in respect of Claims 1, 3, 5, 8, 11, 13, 15, 18, 21, 23, 25, 28, and 36-49 as these claims have been cancelled without disclaimer or without prejudice. These claims are not being cancelled for any reason

pertaining to patentability, and are cancelled to expedite prosecution of remaining claims of the application.

A full, clear, concise and exact description of the features of the pending claims and their interconnection is provided throughout the specification and drawings. The pending independent claims all refer to SEQ ID NO:1. SEQ ID NO:1 is a GM-CSF coding sequence that is optimized for expression in a plant and this sequence is provided in the sequence listing in full, clear, concise and exact terms. Furthermore, plant optimization of sequences is extensively described at paragraphs [0055] to [0060] of the specification. Certain independent claims (claims 4, 14, and 24) refer to a fragment of SEQ ID NO:1 that retains GM-CSF activity of supporting proliferation of TF-1 cells. Fragments are clearly described within the specification, for example, at paragraph [0040] and methods of preparing fragments are well known in the art. Results of assaying GM-CSF activity with respect to proliferation of TF-1 cells are shown in Figure 4. Independent claims 4, 14 and 24 also refer to a glutelin regulatory region. Glutelin (Gt) regulatory regions are clearly described in the specification and drawings, for example see Figure 1, or paragraphs [0014] or [0049], and further use of a Gt1 regulatory region is exemplified in Example 1. Accordingly, the pending claims satisfy the written description requirement.

The pending claims are enabled by the specification and drawings. Example 1 demonstrates that GM-CSF can be expressed in a cereal plant. Prior to Applicants' present disclosure, plant expression of GM-CSF had been restricted to tobacco. Protein production methods in tobacco cannot be assumed to readily transfer to cereal plants due to inherent differences in these plant types, for example, tobacco is a dicot, while cereal plants are monocots. Prior to Applicant's disclosure a person skilled in the art would have no expectation of success for extending expression of GM-CSF from tobacco to cereal plants. However, as a result of Applicants' present disclosure, the skilled person is now certain that GM-CSF can at least be expressed in rice plants. Given Applicants' disclosure, the skilled person can now reasonably predict that GM-CSF may be expressed in various cereal plants. Also, the skilled person would reasonably expect that derivatives or fragments that are known to retain GM-CSF activity could be expressed in cereal plants. For example, there is a reasonable expectation that the GM-CSF coding sequence of SEQ ID NO:1 can be properly

expressed, as its protein product comprises the amino acid sequence of mature human GM-CSF that was produced in Example 1. As another example, GM-CSF fragments that retain GM-CSF activity are known in the prior art (for example see Kaushansky et al. 1989. PNAS, 86:1213-17) and corresponding fragments of SEQ ID NO:1 would be readily apparent to the skilled person and would reasonably be expected to be expressed in cereal plants.

Accordingly, Applicants submit that the pending claims comply with the written description requirement and are properly enabled by the specification to allow the skilled person to make and use the present invention. Accordingly, withdrawal of the Examiner's rejection is respectfully requested.

**Claim Rejections Under 35 U.S.C. 112, second paragraph**

Examiner has rejected claims 32 and 34 contending that these claims do not limit subject matter for the reason that a "DNA vector is a genetic construct". Applicants' agree with Examiner that a DNA vector is a type of genetic construct. However, a genetic construct is not necessarily a DNA vector. A genetic construct may be as simple as a regulatory region operably linked to a coding sequence, or may be even simpler, and may not have element(s) that are typical to a DNA vector. The recitation of DNA vector specifies that such DNA vector element(s) may be present. As such claims 32 and 34 are limited, at least, to a combination of DNA vector element(s) and GM-CSF coding sequence while the independent claims of the application have no limitations with respect to DNA vector element(s). Accordingly, withdrawal of Examiner's rejection is respectfully requested.

Examiner's rejection of claim 38 is moot in view of its cancellation without prejudice or disclaimer.

**Claim Rejections Under 35 U.S.C. 102 and/or 103**

Examiner has cited prior art and has raised several rejections on the basis. Applicants note that each of Examiner's rejections is moot in respect of Claims 1, 3, 5, 8, 11, 13, 15, 18, 21, 23, 25, 28, and 36-49 as these claims are cancelled without disclaimer or without prejudice. Furthermore, the pending independent claims refer to SEQ ID NO:1, with certain of these independent claims (claims 4, 14, and 24) also referring to

a fragment of SEQ ID NO:1 that retains GM-CSF activity of supporting proliferation of TF-1 cells. None of the citations on record teach or suggest a GM-CSF coding sequence as set forth in SEQ ID NO:1, or a fragment thereof that retains GM-CSF activity of supporting proliferation of TF-1 cells. Furthermore, none of the cited references suggest that the nucleotide of SEQ ID NO:1, or fragments thereof may be expressed in rice. For at least these reasons, the pending claims are neither anticipated nor obvious in view of the cited art. Accordingly, withdrawal of each of Examiner's rejections under 35 U.S.C. 102 and/or 103 is respectfully requested.

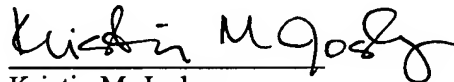
It is respectfully submitted that the above-identified application is now in a condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

No fees are believed to be due in connection with this reply. However, the Director is hereby authorized to charge any payments that may be due to Wilmer Cutler Pickering Hale and Dorr LLP Deposit Account No. 08-0219.

Respectfully submitted,

Wilmer Cutler Pickering  
Hale and Dorr LLP

Date: October 20, 2005



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**Amendments to the Drawings:**

Please replace drawing pages 4/6 and 6/6 with the attached Replacement Sheets 4/6 and 6/6.

The attached Annotated Sheets identify the amendments to the drawings. Figure 4 at page 4/6 has been amended to remove the title for the graph and Figure 6 at page 6/6 has been amended to include sequence identifiers.

Attachment: Replacement Sheet (2 pages)  
Annotated Sheet (2 pages)

Biological activity assay of GM-CSF from Transgenic Rice (Plant#1) on human IF-1 cells

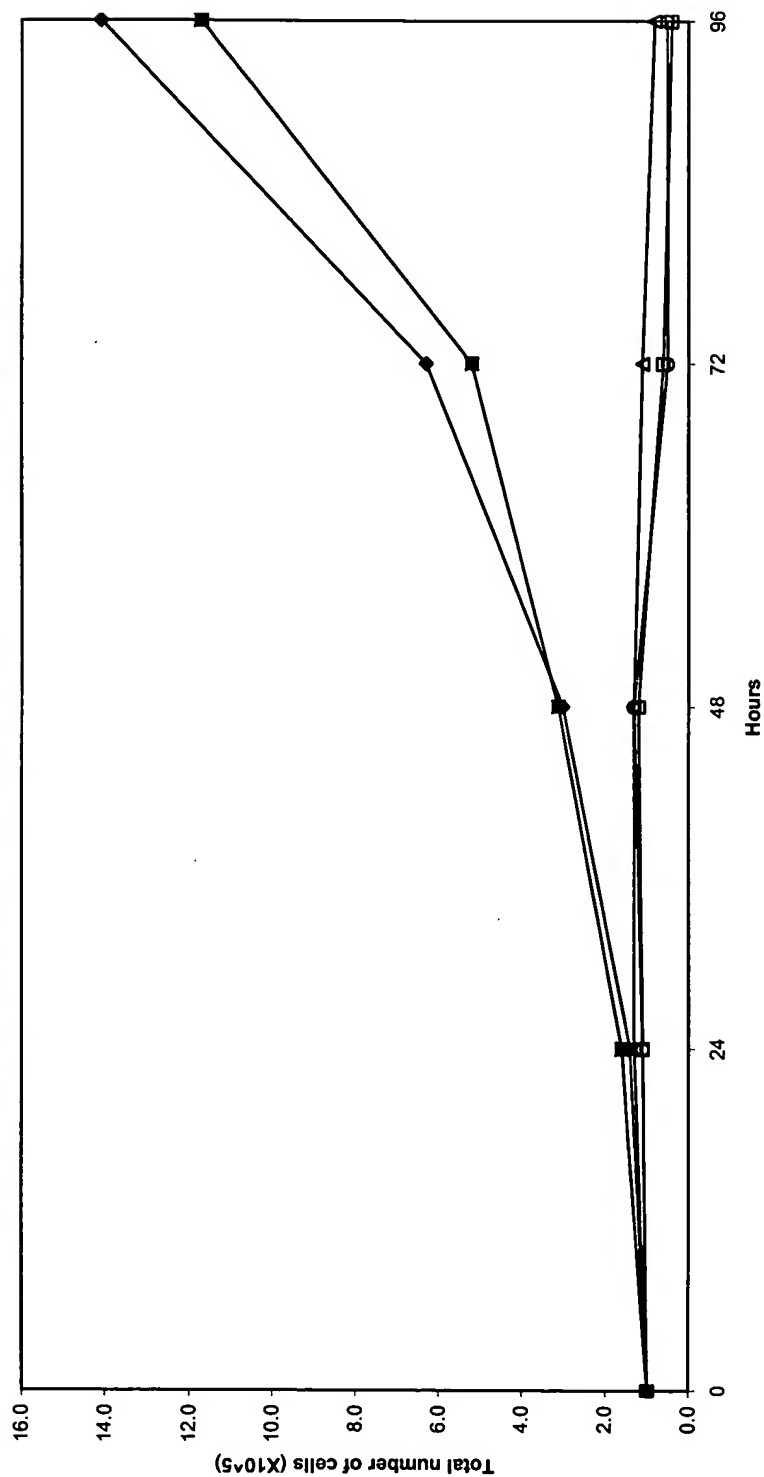


FIGURE 4

### FIGURE 6